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IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

GENETICS INSTITUTE, INC.,
AND CHUGAI PHARMACEUTICAL CO., INC.,
Petitioners,

v.

AMGEN, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* OF THE AMERICAN TYPE CULTURE COLLECTION IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*

The American Type Culture Collection (ATCC) was established in 1925 as a non-profit organization. The ATCC serves researchers and developers in the biological sciences as an archive of living cultures and genetic materials — the ultimate depository for countless scientific investigations throughout the world. In providing its users with reliably characterized, quality-controlled biological cultures, the ATCC has become a global microbiological "Bureau of Standards."

Amicus takes no position on the ultimate outcome of the litigation between petitioners and respondent, and files this brief only to apprise the Court of the vital importance of culture deposits to biological research and applied biotechnology development, and to inform the Court of the threat that the Federal Circuit's decision poses to the "Progress of Science and the useful Arts." Art.I, § 8, cl. 8.

The ATCC received its first deposit made for patent purposes in 1949, long before it was a requirement of the United States Patent and Trademark Office (PTO). Since that time, the ATCC has worked closely with the PTO and other national patent authorities throughout the world to establish rules and guidelines governing bioculture deposits by patent applicants. The ATCC was approved in 1981 as the first International Depository Authority (IDA) under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure.[1]

The ATCC is directed by and for the scientific community. The ATCC's Board of Directors comprises representatives from the major North American scientific and technological societies, including the National Academy of Sciences, the National Research Council, the American Society for Microbiology, the American Association of Immunologists, the American Society of Human Genetics, the Pharmaceutical Manufacturers Association, and the Society for Industrial Microbiology.[2]

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[1] The Treaty requires signatories to recognize a deposit with any IDA that has been approved by the World Intellectual Property Organization. No nation may impose requirements different from or additional to those set forth in the Treaty. The Treaty has 24 signatories, including the United States.

[2] Other organizations represented on the ATCC's board are: The American Institute of Biological Sciences, the American Phytopathological Society, the American Society for Biochemistry and Molecular Biology, the American Society for Cell Biology, the American Society for Virology, the American Society of Parasitologists, the American Society of Tropical Medicine and Hygiene, the American Society of Zoologists, the Canadian Federation of Biological Societies, the Canadian Society of Microbiologists, the Genetics Society of America, the Infectious Diseases Society of America, the Mycological Society of America, the Reticuloendothelial Society, the Society of Protozoologists, and the Tissue Culture Association.

The ATCC's 225 scientific, technical and support staff provide quality control for more than 50,000 deposits of biological material and conduct research into methodology for the characterization and standardization of such material. In addition, the ATCC conducts educational conferences at least once a year to increase knowledge and understanding of the requirements for patent applications in the biological sciences. The ATCC distributes over 150,000 cultures annually to some 10,000 scientists. There are over 9,000 cultures on deposit at the ATCC solely for patent purposes. In 1990, the ATCC received over 8,500 requests from both academic and commercial scientists for cultures from its patent depository.[4]

SUMMARY OF ARGUMENT

The center of gravity for any given course of microbiological research is a bioculture — a sample of the new or unique cells, plasmids or other biological material on which the research is based. Without access to such a sample, the work cannot be reliably verified, reproduced, or improved upon; the new or varied life contained in such samples simply cannot be reduced to a written formula. That is why the scientific community has established public bioculture depositories such as the ATCC, why the industrialized nations have established an international treaty on culture deposits for patent purposes, and why the United States Patent and Trademark Office has mandated deposits by patent applicants claiming inventions involving new, unique or unusual biological material. Publicly

[4] Scientists provide their biological material to the ATCC without charge. The ATCC charges depositors a fee of $600 per deposit to maintain a patent culture for 30 years ($20/year), and it charges those asking for a culture a fee of $45 — $90 for each culture it distributes, in order to cover its costs. Since it is a non-profit organization, and since less than 6% of the biocultures it distributes are from its patent depository, the ATCC has no financial stake in promoting a strong and uniform deposit requirement for biological patents.

accessible deposits of biological material promote progress in, and are essential to ensure comparability and continuity of, biological research.

The decision below has already begun to impede the purposes of the patent regime's deposit rules by introducing uncertainty and disuniformity into deposit requirements. The Federal Circuit has upheld a patent despite a finding that its genetically engineered cell line cannot be reliably reproduced on the basis of the written patent disclosure alone, and despite the patentee's failure to place samples of the cell line in a public depository. Genetic engineers, unlike all other microbiologists working in the biotechnology field, now know that they might be able to get a patent while also keeping their cell lines as trade secrets. These inventors thus have no incentive to make bioculture deposits in the future. That bodes ill for the future of both basic and applied research in genetic engineering, medicine, and other areas of biotechnology.

ARGUMENT

I. PUBLICLY ACCESSIBLE DEPOSITS OF BIOLOGICAL MATERIAL PROMOTE PROGRESS IN, AND ARE ESSENTIAL TO ENSURE COMPARABILITY AND CONTINUITY OF, BIOLOGICAL RESEARCH.

Depositories such as the ATCC exist because microorganisms cannot be adequately described or disclosed with words alone; the nomenclature and judgments of taxonomy are too subjective, and cells and macromolecular biological structures are too variable. Life simply cannot be reduced to a written recipe. Therefore, a deposit of living cells or biologically active cellular materials is necessary in order to put new or unique biological materials into the hands of scientists who

wish to experiment with them. If a picture is worth a thousand words, a cell deposit is worth several million.[4] It was in order to provide a reliable, standardized, central archive for these vital research resources that the ATCC was founded some 66 years ago.

A new era in patenting microbiological inventions emerged in 1949. In that year a patent attorney deposited a sample of the microorganism used to make the antibiotic chlortetracycline with what was then the Northern Regional Research Laboratory of the U.S. Department of Agriculture. The ATCC also accepted its first patent deposit that same year. This inaugurated a practice of making deposits in patent cases whenever a new microorganism was involved. Once a culture deposit has been made, anyone can obtain that microorganism from the depository after the patent has issued; the depositor/inventor cannot hinder or restrict distribution of samples. Biocultures are thus available to all who wish to avail themselves of their freedom under the patent laws to experiment with and improve upon the invention during and after the patent term.[5] This deposit procedure was endorsed and held sufficient to satisfy the disclosure requirements of 35 U.S.C. § 112 in the landmark case of *Application of Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970).

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[4] The PTO has long recognized in other fields as well that words may be insufficient to set forth an invention in a patent application. Historically, the PTO required working models for patents describing mechanical and electrical devices. Today, the PTO requires drawings under 35 U.S.C. § 113 to augment written patent application descriptions where necessary for understanding the invention (*see* 37 C.F.R. § 1.81); working models (37 C.F.R. § 1.92), specimens of chemicals (37 C.F.R. § 1.93), and drawings and specimens of asexually propagated plants (37 C.F.R. §§ 1.165 and 1.166), may be required in appropriate cases as well.

[5] See, e.g., *Whittemore* v. *Cutter*, 29 Fed.Cas. 1120, 1121 (C.C.D.Mass. 1813) (No. 17,600) (Story, J.) (experimental use is not patent infringement); *Eli Lilly & Co.* v. *Medtronic, Inc.*, 872 F.2d 402, 405-06 (Fed.Cir. 1989) (same); *Yarway Corp.* v. *Eur-Control USA*, 775 F.2d 268, 277 (Fed.Cir. 1985) (patent system is designed to encourage others to "design around" patented inventions).

The deposited microorganisms at issue in *Argoudelis* and the other early cases were not being patented as compositions of matter *per se*, but as part of a patented process or as otherwise related to a patent application. When the issue of patentability of new microorganisms themselves came before this Court in *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980), a primary argument advanced in favor of patentability was that patent protection would ensure that cell lines would be deposited as part of patent applications, rather than kept as trade secrets. The American Society for Microbiology (ASM), one of *amicus* ATCC's affiliated organizations, quite correctly explained that "[t]he absence of patenting, therefore, would preclude acquisition of strains by researchers and would inhibit the exchange of information that is vital to research." Brief *Amicus Curiae* of the ASM in *Diamond* v. *Chakrabarty*, No. 79-136 at 11.

Similarly, the Pharmaceutical Manufacturers Association (PMA), another of the ATCC's affiliated organizations, informed the Court in *Chakrabarty* that the maintenance of trade secrets in the form of proprietary cell strains " 'tends to stifle the free exchange of technology and hinders the progress of science by postponing the benefits to mankind of these technologies.' " Brief *Amicus Curiae* of the PMA at 13 (quoting the President's *Industrial Advisory Subcommittee Report on Patent Policy* 159 (1979)).[6]

Since *Chakrabarty*, there has been an explosion in microbiological and biotechnology research. While the *incentive* for the rapid expansion of this field and industry came from *Chakrabarty's* legal ramifications — that is, man-made life forms may be patented — the *pragmatic prerequisite* for that explosive growth came from *Chakrabarty's* practical consequence

[6] *See also* Brief *Amicus Curiae* of the Regents of the University of California in *Chakrabarty* at 22 n.35 ("The fact that a new microorganism can be fully 'described' only by a reference to a physical specimen, rather than in words, makes it particularly susceptible to suppression as a trade secret known to an elite few.").

— that is, inventors made deposits of their unique biocultures as part of their patent applications. Without the uniform placement by patent applicants of sample biocultures with public depositories such as the ATCC, biotechnology and genetic engineering could not have come so far, so fast.

The value of a bioculture deposit lies in the fact that scientists know precisely what they are working with. Their experiments and results are therefore *comparable* with those of other scientists who have worked on the same subject. The pioneering work of others can be verified, replicated, and built upon. A scientist and his graduate students or lab assistants do not have to waste time and resources stumbling around *searching* for square one — they can simply obtain a sample of it from a public depository. Researchers do not have to reinvent the wheel before trying to improve upon it.

Deposits thus save taxpayers, who fund millions of dollars worth of bioresearch every year, countless dollars, because universities and foundations who receive federal funds do not have to spend months or years trying to find the starting point. Without deposits, much research would become prohibitively expensive and never undertaken. Worse still, much sophisticated microbiological work, such as that involving recombinant DNA, could never be accomplished because the randomness inherent in these laboratory and cellular processes make work absolutely irreproducible unless a deposit is available, no matter how much money is invested. As both the Federal Circuit and the district court noted in this very case, without deposits by Amgen of its best mode cell line, "no scientist could ever duplicate exactly the best mode used by Amgen." (Appendix to Petition for Writ of Certiorari at A22).

II. THE FEDERAL CIRCUIT'S DECISION HAS ALREADY BEGUN TO IMPEDE THE PURPOSES OF THE PATENT REGIME'S DEPOSIT RULES BY INTRODUCING UNCERTAINTY AND DISUNIFORMITY INTO DEPOSIT REQUIREMENTS.

Prior to the Federal Circuit's decision in this case, everyone in the field of genetic engineering knew what the rules were. Deposits of cell strains, plasmids or other biological material were required as part of a patent application if those materials were not readily available or reproducible from the patent disclosure. By definition, cells genetically engineered in a lab from the genetic material of entirely different species fell into this category. Thus, for example, petitioner Genetics Institute made multiple deposits of its mammalian Chinese hamster ovary host cells transfected with the human EPO gene as part of its patent application. This was the rule as applied by the Patent Office, as is evident from the many thousands of deposits that have been made in connection with other biotechnology patents in the decade since *Chakrabarty* was decided.

Indeed, the events surrounding the very first genetic engineering patent underscored the importance of making public deposits. One of the seminal patents of Drs. Cohen and Boyer, which set forth the basic tools of genetic engineering, was only days away from being issued by the Patent Office when stories spread in the patent literature and the media that the best mode set forth in the patent, a particular plasmid called pSC101, could *not* be precisely reproduced by following the written disclosures contained in the patent.[7] No culture of the

[7] The article that revealed the best mode defect in the Cohen-Boyer patent was Halluin, *Patenting the Results of Genetic Engineering Research: An Overview*, in BANBURY REPORT 10: PATENTING OF LIFE FORMS 88-89 & nn. 74-75 (1982). The saga of the Patent Office's withdrawal of the patent attained worldwide notoriety, as aptly reported in, *e.g.*, 218 SCIENCE 868 (Nov. 26, 1982); NATURE Nov. 11, 1982, at 95; BIOTECHNOLOGY NEWSWATCH, July 5, 1982, at 1; CHEMICAL WEEK, Aug. 11, 1982, at 12; NEW SCIENTIST, Nov. 4, 1982, at 277.

plasmid had been deposited when the patent application was filed. Since the patent's compliance with the best mode disclosure requirement of 35 U.S.C. § 112 was therefore obviously dubious, the Patent Office *sua sponte* withdrew the patent from issue and reopened prosecution to consider, among other issues, the best mode question. The issue of full disclosure (and hence reproducibility) of the best mode was ultimately resolved by Dr. Cohen's declaration that he had in the past provided and would continue to provide cultures of his plasmid to other researchers from his own laboratory, and by Dr. Cohen's eventual deposit of the plasmid with the ATCC.[8]

In light of the worldwide publicity received by the Cohen-Boyer imbroglio, it obviously behooved inventors to make deposits to ensure fulfillment of both the enablement *and* the best mode requirements of § 112, or to run the risk that their patents would be invalidated if it turned out that the written disclosure did not allow the precise best mode plasmid or cell line to be reproduced. *But all this changed with the Federal Circuit's decision below*. That decision holds that patents involving genetically engineered materials, as distinguished from microbiological patents involving cells or cellular material found in nature, can be upheld even if the best mode cell strain cannot be reproduced from the written description alone, and even if no deposit of that best mode cell strain has ever been made. The Federal Circuit deemed it sufficient that the written disclosure enables others skilled in the art to produce *something like* the best mode cells. (Cert.Pet.App. A21-A23). But this simply and wrongly merges the best mode requirement with the entirely distinct enablement requirement also contained in

[8] Dr. Cohen did not deposit his pSC101 plasmid with the ATCC until June 25, 1981 — 6 months after his original genetic engineering patent issued. At that time, the law required that all necessary deposits be made by the date the patent application was filed. The Federal Circuit has since held that it is sufficient if such deposits are made before the patent actually issues. *See In re Lundak*, 773 F.2d 1216 (Fed.Cir. 1985).

§ 112. The Federal Circuit has effectively rewritten § 112 to make "best mode" and "enablement" a single test in the field of genetic engineering, even though they remain, in every other field of technological endeavor, what Congress surely intended them to be in every instance — separate and distinct legal requirements.[9]

Even if the Federal Circuit should, on some future occasion, apply its new analysis to void a patent for lack of proper cell deposits because the written description does not *enable* one to replicate something like the best mode cells, it will then have enforced only 35 U.S.C. § 112's *enablement* requirement, and will not have enforced the separate *best mode* requirement. The scientific community and the public will receive, in exchange for the grant of a 17-year patent monopoly, not *full* disclosure, but only partial, enabling disclosure; not the full fruit of the inventor's discovery, but only something less. If a patent applicant knows that he can receive a patent monopoly while keeping his best mode cell line as a trade secret, he or she has no incentive to place samples of that cell line in a public depository. It is reasonable to assume that the practice of withholding the best mode biocultures will become widespread.[10] Consequently, the flow of vital biological resources on which research and advancement in genetic engineering depend will diminish.

In particular circumstances, this secrecy might be good for a given company's balance sheet, but *amicus* ATCC is concerned with the welfare of the entire scientific community, and

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[9] *See, e.g., Chemcast Corp.* v. *Arco Industries Corp.*, 913 F.2d 923 (Fed.Cir. 1990); *Dana Corp.* v. *IPC Ltd. Partnership*, 860 F.2d 415 (Fed.Cir. 1988); *Spectra-Physics, Inc.* v. *Coherent, Inc.*, 827 F.2d 1524 (Fed.Cir.), *cert. denied*, 484 U.S. 954 (1987); *Union Carbide Corp.* v. *Borg-Warner Corp.*, 550 F.2d 355 (6th Cir. 1977).

[10] *See* Halluin & Wegner, *Amgen and Scripps: The New Biotechnology Practice*, 10 Biotechnology Law Report 191, 208 (1991); Bioworld, March 13, 1991, at 2.

this secrecy leaves that community — and society at large — all the poorer. In the short term, the cost will show up in the potential technological and medical applications and improvements that will become too expensive or too difficult to investigate or pursue. In the long term, the social and scientific cost will show up in the basic research that is not performed now — basic research of the sort that, decades ago, laid the foundation for genetic engineering and the entire biotechnology field.

CONCLUSION

Amicus is not interested in the outcome of the patent infringement litigation between petitioners and respondent. But the adverse impact that the decision below will have on the public availability of bioculture deposits, and hence its impact on the advancement of science and its consequent impact on society, are far too serious to go unreviewed.

The Federal Circuit's decision threatens to stifle the useful arts of biotechnology, rather than to promote them. In *Chakrabarty*, this Court provided the much-needed stimulus to biotechnology. Not since then has it been so important that this Court correct the course of the law so that the fragile, young biotechnology industry can grow and benefit mankind as it has for the last decade. The ATCC urges this Court to grant the writ and give this momentous decision plenary attention.

Respectfully submitted,

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